

REMARKS

Claims 1-2, 5-6 and 11 have been rejected under 35 U.S.C. 102(e) as being anticipated by Koch '064 (U.S. Patent No. 5,510,064). Dependent claims 12-17, 19-27 and 39-43 have been rejected as obvious in view of Koch '064 combined with Mohajer in view of Shields.

In order to expedite prosecution, Applicant has amended the specification and submitted a new Declaration and Power of Attorney, claiming priority from Koch '064 (U.S. Serial No. 07/989,089) and U.S. Serial No. 08/462,071 under 35 U.S.C. §120. The parent to this application (U.S. Serial No. 08/985,012) and U.S. Serial No. 08/462,071 were co-pending, and U.S. Serial No. 08/462,071 and the application resulting in Koch '604 were co-pending. All of the applications and Kraus '064 have at least one inventor in common, i.e., James Koch.

An unsigned copy of a Supplemental Declaration and Power of Attorney is submitted herewith. A signed copy will be forwarded under separate cover.

Applicant submits that the rejections under §§102 and 103 are thereby obviated, and respectfully requests that these rejections be withdrawn.

Because of this change in priority claim, which removes Koch '064 as a reference, Applicant has amended the claims to undo the amendments that were made in Applicant's previous response (amendments that were made in response to the rejections based on the Koch '064 reference.)

Claims 17 and 23 have been amended to recite that the cervical cap is custom molded, to further distinguish the Mojaher and Shields references, which describe contraceptive devices that are not custom molded.

New claim 51 is similar to claim 1 of the parent to this application, U.S. Patent No. 5,980,804. However, Applicant has replaced the term "curable" with the term "hardenable". Applicant submits that this change does not affect the patentability of this claim, and respectfully requests that claim 51 be allowed.

Other minor amendments have been made. Claim 1 has been amended to remove the phrase "cured polymeric material." In claim 19, "is" has been replaced by "comprises." Applicant submits that these changes do not affect patentability.

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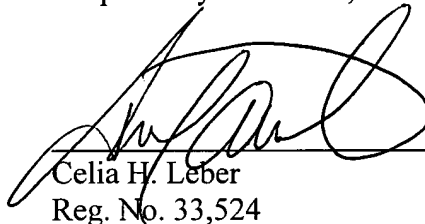
A terminal disclaimer is submitted herewith.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a \$112.00 check for excess claim fees and a \$55.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Version with markings to show changes made

In the specification:

Paragraph beginning at page 1, line 5 has been amended as follows:

--This application is a continuation-in-part of U.S. Serial No. 08/985,012, filed December 4, 1997 and issued on November 9, 1999 as U.S. Patent No. 5,980,804, U.S. Serial No. 08/462,071, filed June 5, 1995 and now abandoned, and U.S. Serial No. 07/989,089, filed December 11, 1992 and issued on April 23, 1996 as U.S. Patent No. 5,510,064.--

In the claims:

Claims 1, 2, 3, 6, 8, 10, 17, 19, 23, 33 and 34 have been amended as follows:

1. A cervical cap comprising:
a rim member dimensioned to fit a patient's exocervix;
a cap dome [of cured polymeric material] extending from the rim member to cover the exocervix and having an opening to allow fluid flow out of the cap dome; and
a valve associated with the opening, constructed to allow outflow while preventing fluid flow into said cap dome [, the valve comprising a membrane disposed over an outer surface of the dome].
2. The cervical cap of claim 1 wherein the valve [further] comprises a check valve sealingly positioned in said opening.
3. The cervical cap of claim 1 wherein the valve comprises a membrane disposed over an outer surface of the dome and [is] sealed to the cap dome in spaced regions.
6. The cervical cap of claim 1 wherein the valve [further] comprises a collapsed tube valve.

8. The cervical cap of claim [1] 3 wherein the membrane has a thickness of less than 0.5 mm.

10. The cervical cap of claim [1] 3 wherein the membrane comprises a silicone polymer.

17. A cervical cap comprising a custom molded cap body constructed to cover the exocervix and prevent ingress of sperm and fluids, and a portion, associated with the cap body, that is impregnated or coated with a therapeutic agent and is constructed to release the therapeutic agent over a period of time during use of the cap [, the portion being removable and replaceable].

19. The cervical cap of claim [17] 18 wherein said portion [is] comprises a removable ring that is press-fit onto the cap adjacent the rim.

23. A method of protecting the exocervix of a female, comprising applying to the exocervix a custom molded cervical cap that includes a portion that is impregnated or coated with a therapeutic agent, the portion being constructed to slowly release the therapeutic agent during use of the cap.

33. A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination [a ring gauge for measuring an exocervix,] a rim member dimensioned to fit an exocervix, a curable material, and a means for applying the curable material.

34. A kit for use by a clinician in forming a custom cervical cap in situ, in a patient's body, comprising in combination [a ring gauge for measuring an exocervix,] a rim member dimensioned to fit an exocervix, a shell member dimensioned to be mounted on said rim member, a curable material, and a means for applying the curable material.